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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,311	07/19/2001	Heiner Max	Beiersdorf 733-KGB	9953

7590 03/12/2003
Norris McLaughlin & Marcus PA
220 East 42nd Street
30th Floor
New York, NY 10017

EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,311

Applicant(s)

MAX ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2002 has been entered in Paper No. 14.

This Office Action is a response to Applicant's request for continued examination (RCE) filed December 19, 2002 in Paper No. 14, and amendment and response to the Final Office Action (mailed July 25, 2002), filed December 19, 2002 in Paper No. 15 wherein claims 8, 10-12 and 14-23 are cancelled and claims 24-34 are newly submitted. Currently, claims 24-34 are pending in this application.

It is noted that this application claims priority to German 100 39 063.3.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed with the instant Application. Claims 24-34 are examined on the merits herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez et al. (5,296,472, PTO-982).

Sanchez et al. discloses methods for delipidation of skin and/or hair, or for controlling the excessive buildup of sebum on mammalian skin or hair comprising topically applying to skin and/or hair an effective amount of a composition comprising a cyclodextrin component having one or more cyclodextrin. See abstract, col.1 lines 14-17 and 31-33, col.3 lines 13-14 and 61-65, and col.8-9 Example 3-5, in particular. Sanchez et al. also discloses that the effective amounts of cyclodextrin component in the topical composition therein are about 1-30% by weight and most preferably 10% by weight, within the instant claims. See col.2 lines 57-63 in particular. Hence, Sanchez et al. methods inherently reducing the production of sebum in skin and/or hair. See *Ex parte Novitski*, 26 USPQ 2d 1389. In this regard, reducing the production of sebum in skin and/or hair is an inherent property in the administration to skin and/or hair (topically) of cyclodextrins. See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881(Fed. Cir. 2001). Therefore, Sanchez et al. anticipates Claims 24-26 and 28-29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 even though it is not anticipated by Sanchez et al. (5,296,472) as applicable to claims 24-26 and 28-29, is rejected under 35 U.S.C. 103(a) as being unpatentable over the same reference by Sanchez et al. (5,296,472).

Sanchez et al. discloses methods for delipidation of skin and/or hair, or for controlling the excessive buildup of sebum on mammalian skin or hair comprising topically applying to skin and/or hair an effective amount of a composition comprising a cyclodextrin component having one or more cyclodextrin. See abstract, col.1 lines 14-17 and 31-33, col.3 lines 13-14 and 61-65, and col.8-9 Example 3-5, in particular. Sanchez et al. also discloses that the effective amounts of cyclodextrin component broadly including α -, β -, γ -cyclodextrins in the topical compositions therein are about 1-30% by weight and most preferably 10% by weight, within the instant claims. See col.2 lines 57-63 in particular.

Sanchez et al. does not expressly disclose the composition therein comprising at least 30% weight of γ -cyclodextrin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the composition therein comprising at least 30% weight of γ -cyclodextrin.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the composition therein comprising at least 30% weight

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of γ -cyclodextrin since the effective amounts of cyclodextrins broadly including α -, β -, γ -cyclodextrins in the topical compositions therein employing in the methods therein are known to be about 1-30% by weight according to Sanchez et al. Therefore, one of ordinary skill in the art would have found it obvious to employ at least 30% weight of the particular known cyclodextrin, γ -cyclodextrin, in Sanchez's compositions. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez et al. (5,296,472)

Sanchez et al. discloses methods for delipidation of skin and/or hair or for controlling the excessive buildup of sebum on mammalian skin or hair comprising topically applying to skin and/or hair an effective amount of a composition comprising a cyclodextrin component having one or more cyclodextrin. See abstract, col.1 lines 14-17 and 31-33, col.3 lines 13-14 and 61-65, and col.8-9 Example 3-5, in particular. Sanchez et al. also discloses that the effective amounts of cyclodextrin component broadly including α -, β -, γ -cyclodextrins in the topical composition therein are about 1-30% by weight and most preferably 10% by weight. See col.2 lines 57-63 in particular. Sanchez et al. further discloses that the cyclodextrin compositions therein may be creams, gels, solutions suspensions; the cyclodextrin compositions therein may further

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comprise oils, waxes and other type of lipid-type agents known commonly used for skin treatment (see col.5 lines 12-20 in particular).

Sanchez et al. does not expressly disclose a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin. Sanchez et al. also does not expressly disclose this particular composition comprising at least 30% weight of γ -cyclodextrin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin in the claimed method herein and to employ this particular composition comprising at least 30% weight of γ -cyclodextrin.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin in the claimed method herein because it is known that the compositions of Sanchez et al. comprising a cyclodextrin component having one or more cyclodextrin for skin and hair treatments therein may further comprise oils, waxes and other known lipid-type agents, which are also an known oil phase. Therefore, one of ordinary skill in the art would have found it obvious to further employ an oil phase such as oils, waxes and other known lipid-type agents in a particular composition of Sanchez et al.

As discussed above, one having ordinary skill in the art at the time the invention was made would have been motivated to employ this particular composition comprising

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at least 30% weight of γ -cyclodextrin since the effective amounts of cyclodextrins broadly including α -, β -, γ -yclodextrins in the topical compositions therein employing in the methods therein are known to be about 1-30% by weight according to Sanchez et al.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks in Paper No. 15 filed on December 19, 2002 with respect to the rejections of cancelled claims 8, 10-12 and 14-23 made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered and but are but are moot in view of the new ground(s) of rejections set forth above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

A handwritten signature in black ink, appearing to read 'S. Anna Jiang', is positioned above the printed name.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 27, 2003